K070546

Bio-Rad Laboratories
Lyphochek Diabetes Control
Summary of Safety and Effectiveness

APR - 2 2007

1.0 **Submitter**

Bio-Rad Laboratories
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Contact Person

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Date of Summary Preparation

February 23, 2007

2.0 **Device Identification**

Product Name:	Lyphochek Diabetes Control
Common Name:	Hematology and Pathology Devices Hematology quality control mixture
Classifications:	Class II
Product Code:	GGM
Regulation Number:	21 CFR 864.8625

3.0 **Device to Which Substantial Equivalence is Claimed**

Lyphochek Diabetes Control
Bio-Rad Laboratories
Irvine, California 92618

510 (k) Number: K862186

4.0 **Description of Device**

This is a lyophilized product prepared from human whole blood containing preservatives and stabilizers.

5.0 **Intended Use**

Lyphochek Diabetes Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

6.0 Comparison of the new device with the Predicate Device

Lyphochek Diabetes Control claims substantial equivalence to the Lyphochek Diabetes Control currently in commercial distribution (K862186). Both of these controls are manufactured with exactly the same formulation. The only difference between the predicate device and the new Lyphochek Diabetes Control is that new product has claims for Total Hemoglobin and the predicate device does not.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	**Bio-Rad Laboratories** Lyphochek Diabetes Control (New Device)	**Bio-Rad Laboratories** Lyphochek Diabetes Control (Predicate Device K862186)
	Similarities	
Intended Use	Lyphochek Diabetes Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Lyphochek Diabetes Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Matrix	Human Whole Blood based	Human Whole Blood based
Preservatives	Contains preservatives	Contains preservatives
Form	Lyophilized	Lyophilized
Storage (Unopened)	2°C to 8°C Until expiration date	2°C to 8°C Until expiration date
Open Vial Claim	7 days at 2 to 8°C	7 days at 2 to 8°C
	Differences	
Analytes	Claims: ▪ Hemoglobin A1C ▪ Hemoglobin A1 ▪ Hemoglobin F ▪ Total Glycated Hemoglobin ▪ Total Hemoglobin	Claims: ▪ Hemoglobin A1C ▪ Hemoglobin A1 ▪ Hemoglobin F ▪ Total Glycated Hemoglobin Does not Claim ▪ Total Hemoglobin

7.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for this control. Product claims are as follows:

- Open vial Stability: 7 days at 2 to 8°C.
- Shelf Life: 3 Years at 2 to 8°C

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Bio-Rad Laboratories, QSD
c/o Elizabeth Platt
Regulatory Affairs Manager
9500 Jeronimo Road
Irvine, California 92618

APR - 2 2007

Re: k070546
Trade/Device Name: Lyphochek Diabetes Control
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture.
Regulatory Class: Class II
Product Code: GGM
Dated: February 23, 2007
Received: February 26, 2007

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070546

Device Name: **Lyphochek Diabetes Control**

Indications For Use: **Lyphochek Diabetes Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.**

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K070546